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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/303,518	04/30/1999	VINCENZO SCARLATO	CHIR-0160	8470

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	PAPER NUMBER
1631	28

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/303,518	Applicant(s) SCARLATO ET AL.	
	Examiner Shubo "Joe" Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-13* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 April 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8, 18
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' election without traverse of Group II (claims 2-3, and 8-13) and the nucleotide sequences of SEQ ID NOs:125, 127, 131, 463, 465, 569, 571, 649, 651, and 653, in Paper # 27, filed 6/28/02, are acknowledged.

Claims 2-3 are drawn to nucleic acid molecules comprising sequence of SEQ ID NO:1, 3, 5, or 7, or polynucleotides that encode the amino acid sequence of SEQ ID NO:2, 4, 6, or 8. Since these sequences were not elected in Paper No. 27, claims 2-3 are drawn to non-elected inventions.

Accordingly, claims 1-17 are currently pending. Claims 8-13 are under examination. Claims 1-7 and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected inventions, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 27.

Priority

It is brought to applicants' attention that for the purpose of examination, priority has not been granted to the claimed international application of PCT/IB98/01665 because no certified copy of the application is submitted to the Office. Further, the Office has not been able to determine that the elected invention, i.e. the elected sequences, was disclosed in the claimed PCT application. Prior art published after the claimed provisional application but before the filing date of the instant application may have been cited in this Office action. The applicants are requested to provide evidence that the elected invention is indeed disclosed in the claimed PCT application if they wish to contest the citation of the intervening prior art.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because certain sequences are not listed in the Sequence Listing, e.g. those in Figure 21A, etc. and those on page 52, etc. A paper copy and a computer readable form of a new Sequence Listing and a statement under 37 CFR 1.821(f) are required. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Drawings

Note the attached Notice of Draftsperson's Patent Drawing Review. Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Applicants are required to submit drawing corrections within the

time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Specification

The specification is objected to because of the following:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed. The title is directed to Neisserial antigens, which are peptides, whereas the elected invention is directed to Neisserial polynucleotides.

In the 'Brief Description of the Drawings", the specification refers to Figures 1-20 and Figure 21 (page 49), whereas the actual drawings are Figures 1A-1E, Figures 2A-2B, etc. Figures 1A-1E are actual figures, not part of Figure 1.

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

It would be readily recognized by an ordinary skilled in the art that claims 8-13 read on nucleic acid molecule that naturally occurs in a Neisserial cell, i.e. the nucleic acid molecule of the entire "chromosomal" DNA of the cell (the whole "chromosomal" DNA is one molecule) because the nucleic acids with the sequences of the elected SEQ ID NOs are isolated from Neisserial cells. Hence, the claims are drawn to non-statutory subject matter. However, an "isolated" nucleic acid molecule comprising a sequence of the elected SEQ ID NOs would not read on nucleic acid molecule that naturally occurs in a Neisserial cell.

Specifically, for claim 8, the naturally occurring nucleic acid molecule of a Neisserial cell indeed encodes a protein of claims 4-6, e.g. the protein of SEQ ID NO: 126 which is a Neisserial protein encoded by the sequence of the elected SEQ ID NO:125 (see pages 135-136 of the specification). For claim 9, the naturally occurring nucleic acid molecule of a Neisserial cell comprises any of the sequences of the elected SEQ ID NOs because these sequences are derived from the Neisserial cell itself. For claim 10, the naturally occurring nucleic acid molecule of a Neisserial cell comprises a fragment of any of the sequences of the elected SEQ ID NOs again because the fragment of these sequences are derived from the Neisserial cell itself. For claim 11, the naturally occurring nucleic acid molecule of a Neisserial cell complements to any of the sequences of the elected SEQ ID NOs or fragments thereof because these sequences are derived from Neisserial cells, and the naturally occurring nucleic acid molecule of a Neisserial cell is double-stranded, containing both the sequences of the elected SEQ ID NOs (the sense strand) and the complement sequences (the anti-sense strand). For the

same reasons, the naturally occurring nucleic acid molecule of a Neisserial cell comprises sequences that are at least 50% (actually 100%) identical to the sequences of the elected SEQ ID NOs (as required in claim 12), and can hybridize to the sequences of the elected SEQ ID NOs (as required in claim 13).

Claim Rejections-35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 9-13 are drawn to nucleic acids/polynucleotides comprising the sequences of the claimed SEQ ID NOs or fragments thereof. Given the broad scope of the claims due to the use of the open language "comprising", they are drawn to a genus: any nucleic acid that minimally contains the sequences of the claimed SEQ ID NOs, including any full length genes, any fusion constructs, etc. There is substantial variability among the species of polynucleotides or nucleic acids encompassed within the scope of the claims because the claimed SEQ ID NOs are only fragments of these full-length genes, fusion constructs, etc. Since the claimed genus encompasses species yet to be discovered, e.g. DNA constructs that encode fusion proteins, etc., the mere disclosure

in the specification of a species: sequences of the elected SEQ ID NOs, does not provide an adequate description of the claimed genus. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs or RNAs encompassed in the claims which comprise the sequences of the claimed SEQ ID NOs.

Furthermore, claims 12-13 are drawn to polynucleotides having at least 50% degree of identity to the sequences of the elected SEQ ID NOs or fragments thereof, a genus containing a great number of species. However, as set forth above, the instant specification only describes a species of nucleic acid consisting of a sequence of the elected SEQ ID NOs. Applicant is advised that absent factual evidence, the specification is not deemed to provide reasonable support to one of ordinary skill in the art that the biochemical activity of a nucleic acid at least 50% but less than 100% identical to the entire length of the elected sequences would be the same. The effects of changes in the structure due to changes of sequences are largely unpredictable as to which ones have a significant effect versus not. Therefore, sequence identity/similarity results in an unpredictable and thus unreliable correspondence between the sequences of the entire sequence of the elected SEQ ID NOs and those only 50% or more, but less than 100% identical.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the SEQ ID Nos elected , the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides/nucleic acids, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human

> insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the SEQ ID Nos elected, but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus is highly variable.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (See page 1115).

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13 are rejected under 35 U.S.C. § 102 (b) or (e) as being anticipated by the various database sequences or US patents listed below.

The various database sequences or US patents listed below disclose nucleic acid sequences wherein they all comprise a fragment of at least 10 base pairs of the sequences of the elected SEQ ID NOs, as required in claim 10 and as defined in the

specification for the term "fragment" (page 4). See the table below and the enclosed sequence alignments.

In regard to claim 11, which is dependent from claim 10, since nucleic acid molecules are double-strand, it would be readily recognized by an ordinary skill in the art that these database entries also disclose, implicitly, the complement sequences of these fragments according to the Watson-Crick theory.

In regard to claim 12, which is dependent from claim 10 or 11, these database entries disclose sequences comprising nucleotide sequence that is at least 50%, actually 100% identical to fragments of the sequences of the elected SEQ ID NOs, or complements thereof.

In regard to claim 13, which is dependent from claim 10, or 11, or 12, since the database entries disclose sequences of claim 10-12, which includes forward sequences (claim 10) and their complements (claim 11), clearly, the complement sequences of 11 can hybridize to the sequences of claim 10

SEQ ID NO	**Database/ acc. no.**	**fragment length (bp)**	**102 sec.**	**Pub. Date**
125	GenEmbl/HIU20229	14	102(b)	2/9/1995
127	GenEmbl/HIU20229	14	102(b)	2/9/1995
131	GenEmbl/HIU20229	14	102(b)	2/9/1995
463	GenEmbl/A61829	18	102(b)	3/9/1998
465	GenEmbl/A61829	18	102(b)	3/9/1998
569	US patent 5763188 (seq15)	14	102(b)	6/9/1998
571	US patent 6127180 (seq45)	10	102(e) filing date: 4/18/97	10/3/2000
651	GenEmbl/AJ001740	>10	102(b)	5/21/1998

649	GenEmbl/AJ001740	>10	102(b)	5/21/1998
653	GenEmbl/AJ001740	>10	102(b)	5/21/1998

Claims 8-13 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Paruchuri et al. (PNAS, USA, Vol. 87, No.1, pages 333-337, 1990).

Paruchuri et al. disclose that they have isolated chromosomal DNA from wild type Neisseria gonorrhoeae (see page 334, left column, under "Southern Hybridization"). It is well known to, and readily recognized by, an ordinary skill in the art that bacterial cell has only one chromosome and the entire chromosome is one huge nucleic acid molecule. Since the nucleic acid sequences of the elected SEQ ID NOs are from Neisseria, it is inherent that the nucleic acid molecules, i.e. the Neisserial chromosomal DNA, disclosed by Paruchuri et al. encode the proteins encoded by the nucleic acid sequences of the elected SEQ ID NOs, as required in claim 8. Clearly, the DNA molecules disclosed by Paruchuri et al. comprise the nucleotide sequences of the elected SEQ ID NOs, and fragments thereof, as required in claims 9 and 10 respectively. It is well known that the Neisserial chromosomal DNA is double stranded, thus, the DNA molecules disclosed by Paruchuri et al. inherently comprise the sequences complementary to the sequences of the elected SEQ ID NOs, or fragments thereof, as required in claim 11. Because the sequences of the elected SEQ ID NOs is derived from Neisserial chromosomal DNA, the DNA molecules disclosed by Paruchuri et al. inherently comprise sequences that is at least 50% identical to the sequences of the elected SEQ ID NOs, or fragments thereof, as required in claim 12. The DNA molecules disclosed by Paruchuri et al. can, inherently, hybridize to the sequences of

the elected SEQ ID NOs, or fragments thereof, or complements thereof, as required in claim 13.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). In the instant case, it is the applicants' burden to prove that the instantly claimed inventions in claims 8-13 do not read on the Neisserial chromosomal DNA molecules disclosed by Paruchuri et al.

Claim Objections

Claim 8, and its dependent claims 9, and 11-13, are objected to because they do not reflect the elected subject matter. Applicant elected polynucleotide comprising a sequence of 10 SEQ ID NOs or fragments thereof while claim 8 depends from any one of claims 4-6, which are drawn to proteins. Amendment of the claims to read on the polynucleotides of the elected SEQ ID NOs is requested.

Claim 9 is objected to because it ends with two periods.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center

1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.
Patent Examiner

MICHAEL BORIN, PH.D
PRIMARY EXAMINER